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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/765,588 04/25/97 HAYWARD

N 10441

EXAMINER

HM22/0417

SCULLY SCOTT MURPHY & PRESSER
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GARDEN CITY NY 11530

SADUD, C

ART UNIT

PAPER NUMBER

1646

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/765,588

Applicant(s)

HAYWARD et al.

Examiner
Christine Saoud

Group Art Unit
1646



☒ Responsive to communication(s) filed on Feb 22, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-25, 28, 30, 33, 34, 37-42, 44-47, 50, and 51 is/are pending in the application.

Of the above, claim(s) 1-25, 34, and 37-42 is/are withdrawn from consideration.

☒ Claim(s) 28, 30, 33, 44-46, and 50 is/are allowed.

☒ Claim(s) 47 and 51 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 17

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Claims 28, 30, 33, 44-47, 50 and 51 have been amended, claims 43, 48 and 49 have been canceled, and claim 51 has been added as requested in the amendment of paper #18, filed 22 February 2000. Claims 1-25, 28, 30, 33-34, and 37-42, 44-47, and 50-51 are pending in the instant application.

Claims 1-25, 34 and 37-42 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 11.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed 08 July 1999 have been fully considered but they are not deemed to be persuasive.

Oath/Declaration

5. The Declaration stands objected to for the reasons of record in paper #13. This objection was repeated in paper #15. Correction is necessary.

Drawings

6. Figures 1-6, 9-11, and 16-17 are still objected to for the reasons of record in paper #13. This objection was repeated in paper #15. Correction of the Brief Description of the Drawings will be required when the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1).

Claim Rejections - 35 USC § 112

7. Claims 47 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 47 and 51 are directed to subject matter of an isolated nucleic acid which has at least about 70% similarity to SEQ ID NO:3 (claim 47) and additionally which hybridizes under low under low stringency conditions to a DNA which encodes a VEGF protein, wherein the hybridization conditions are provided in the specification (claim 51). Applicant argues that “there is no requirement in the patent law that a claim directed to an isolated nucleic acid must recite the protein which is encoded thereby” (see page 4). However, the disclosed, enabled use of the nucleic acid is to make the polypeptide. It is true that one of ordinary skill in the art could make

nucleic acid molecules which meet the structural limitations of the claims, however, one could not use them in any patentable manner unless they actually encoded a protein. The issue of the rejection is a lack of an adequate written description. As stated previously, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein of SEQ ID NO:4. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO:3. The claims are not limited to nucleic acid molecules encoding a protein with a specific amino acid sequence, and actually do not require the nucleic acid to even encode a protein (which is required for the claims to be enabled). The specification contemplates molecules which are VEGF-like but do not have the amino acid sequence of SEQ ID NO:2, including but not limited to, mammalian, bovine, ovine, porcine, equine, rodent, human, birds, fish and reptiles (see page 4 of the specification). The specification only describes one alternatively spliced VEGF protein from human and mouse and fails to teach or describe any other related proteins, let alone from different species or variant forms. Therefore, there is a lack of guidance or teaching regarding structure and function because there are only very limited examples provided in the specification and because there is no guidance found in the prior art. The claims include nucleic acids which share some sequence similarity to the disclosed nucleic acid, however, this sequence similarity is not sufficient to provide a function of encoding a protein which is required for enablement of the claimed invention.

Applicant argues that the nucleic acids of SEQ ID NO:5, 7 and 9 would hybridize under low stringency to the reverse complement of SEQ ID NO:3, therefore "the specification adequately describes examples of nucleic acids capable of hybridizing to SEQ ID NO:3" (see page

5 of response). Applicant should note that it was not alleged that examples were not presented in the specification. However, these examples are not representative of the broad genus that is being claimed, which encompasses a multitude of nucleic acid molecules. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the specific nucleic acid molecules of the Sequence Listing, which are alternatively spliced products of the same gene. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those nucleic acids which hybridize to SEQ ID NO:3 under low stringency conditions) which the specification defines as including different species and variants and the specification teaches a very limited number of embodiments (4 sequences, 2 alternatively spliced products, one pair from human and one pair from mouse). Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention, absent evidence to the contrary.

8. Claims 47 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid molecules which encode naturally occurring VEGF molecules and are capable of inducing vascularization, interacting with a receptor, inducing cell migration, survival, or astroglial cell proliferation, does not reasonably provide enablement for nucleic acid molecules which deviate from the disclosed nucleic acid sequences of the Sequence Listing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Applicant has not specifically argued this rejection. It would appear that any arguments pertaining to enablement have been addressed above in terms of written description.

Conclusion

9. Claims 28, 30, 33, 44, 45, 46 and 50 are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. This application contains claims 1-25, 34 and 37-42 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 14, 2000

CHRISTINE SAOUD
PATENT EXAMINER

Christine Saoud